The specification teaches throughout that encapsidated vector can be used in the practice of the instant invention. The instant specification teaches on page 10 that "AAV vector" means either the DNA or a virus particle.

In the paragraph bridging pages 12 and 13 of the instant specification, the application teaches making virus particles. Some of the benefits of AAV particles as compared to other viral vectors also are cited.

First, the Examiner is requested respectfully to consider the arguments of record in view of the amended claims provided hereinabove.

The hardiness of the AAV virus particle to various environments is known in the art.

Of all the routes of administration available to the artisan, oral administration is perhaps the most challenging because of the many harsh environments an administered drug must endure prior to absorption. Thus, concerns about routes of administration are of lesser import when one considers the success of oral administration of a pharmaceutical as provided with the instant invention.

As evidence of the operability of the claimed invention, applicant previously submitted a publication teaching peroral administration of a vector and successful use thereof.

As further evidence of the enablement of the claimed invention, attached hereto is a copy of During et al., Science 287:1453-1460, 2000, teaching AAV particles carrying the NR1 subunit of the NMDA receptor. Transgene expression persisted for at least 5 months

and antibodies raised to NR1, a brain protein, resulted in an anti-epileptic and neuroprotective activity.

As is known in the art, AAV can carry a variety of different kinds of transgenes. Moreover, a number of different AAV vectors are being used in clinical trials, attesting to the robust enablement of the technology. For example, Loeb et al. (copy attached hereto) teach the delivery of a regulatory element by AAV that was operable in vivo (Human Gene Therapy 10:2295-2305, 1999). Tang et al. (American Journal of Physiology 277, no. 6, pt. 2:H2392-H2399, 1999, copy attached hereto) teach delivery of an antisense molecule by AAV that yielded an observable in vivo effect.

Clearly, the delivery of a variety of different kinds of transgenes by AAV is no longer in question.

The claimed invention relates to the use of an encapsidated AAV vector for gene expression in the gut of an animal. The evidence of record proves the enabling nature of the instant specification and of the claimed invention.

The Examiner raised an issue with respect to means of delivery other than oral.

As argued hereinabove, oral delivery is the most rigorous form of drug delivery known. Thus, the instant invention provides an enabling disclosure for one of the most difficult ways to deliver a pharmaceutical.

Other routes of administration are well known in the art and it is well within the ability of the artisan to extrapolate dosages based on one form of administration to another form of administration. Moreover, the artisan is not limited from practicing routine

experimentation to ascertain and to derive optimal dosages for other delivery routes based on settled pharmaceutical arts.

Hence, it is believed that in view of the claimed invention and the evidence of record, the instant invention clearly is enabled. Accordingly a prima facie case of obviousness has not been made and the rejection should be removed.

IV. On page 11 of the Office Action, claims 1, 10 and 11 were rejected provisionally under the judicially-created doctrine of obviousness-double patenting over claim 7, 19, 20 and 42 a copending application, U.S. Ser. No. 09/510,144.

Because the rejection is provisional, it would be premature to act substantively on the matter. An application with allowable claims should be moved to issuance to avoid delay and any possible patentability issues dealt with in the application not yet allowed. The Examiner indicated that the claims of the co-pending application are more descriptive. However, the level of description is of no moment to patentability. The instant claims and the specification are in compliance with the Patent Statute.

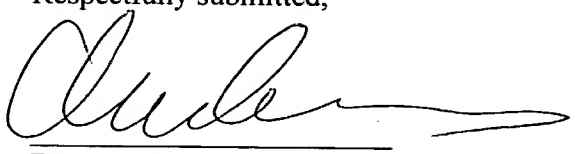
Accordingly, the rejection should be moved and the cased moved to allowance.

CONCLUSION

Applicant has taken substantial steps to advance prosecution. Reexamination, reconsideration, withdrawal of the rejections and early indication of allowance are requested respectfully. If any questions remain, the Examiner is urged respectfully to contact the undersigned at the local exchange provided below.

The Commissioner hereby is authorized to charge payment of any fees under 37 C.F.R. § 1.17 that may become due in connection with the instant application or credit any overpayment to Deposit Account No. 18-2220.

Respectfully submitted,



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MARKED UP CLAIMS
09/559,327

1. (Amended) A method of expressing a gene product in the gut of an animal, which comprises:

administering [a] an encapsidated recombinant AAV vector to the gut of said animal, wherein said vector comprises a non-AAV gene of interest [ligated into an AAV vector] operably linked to a promoter operable in gut.

2. (Amended) The method of Claim 1, wherein said vector is administered [dissolved or suspended in] with a liquid pharmaceutically acceptable carrier.

5. (Amended) The method of Claim 1, wherein said gene of interest comprises a DNA segment encoding a protein operably linked to [a] said promoter operable in [said] gut.